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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/501,504      | 07/15/2004  | Seishiro Mochizuki   | 0152-0694PUS1       | 8266             |

2292 7590 11/01/2007  
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| EXAMINER |
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JAVANMARD, SAHAR

|          |              |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

4133

|                   |               |
|-------------------|---------------|
| NOTIFICATION DATE | DELIVERY MODE |
|-------------------|---------------|

11/01/2007

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

|                              |                               |                                  |  |
|------------------------------|-------------------------------|----------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/501,504 | Applicant(s)<br>MOCHIZUKI ET AL. |  |
|                              | Examiner<br>SAHAR JAVANMARD   | Art Unit<br>4133                 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 6-9, 12-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 10, 11, 17, and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/15/04; 4/24/06</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Claims***

This Office Action is in response to the Response to Restriction Requirement filed on September 17, 2007. Claims 1-18 are pending in this Application. Claims 6-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions. Claims 12-16 are also withdrawn from consideration. The instant claims were not presented in the original claims. Claims 12-16 are directed to a process of making and are a different invention and would have been restricted. Claims 1-5, 10-11, and 17-18 are examined herein as they read on the elected invention.

### ***Election/Restriction***

In response to the Office Action mailed on August 16, 2007, Applicant's election without traverse of Group I, claims 1-5, 10, and 11, directed to agents and pharmaceutical compositions comprising *P. temminckii frass* as an ingredient in the reply filed on September 17, 2007, is acknowledged.

The requirement for restriction is thus made FINAL.

### ***Information Disclosure Statement***

The reference provided referred to as "D2" by the International Search Authority was not listed on the IDS yet provided as prior art. Furthermore, there is no reference on the actual article (i.e., journal title, date, etc...). Examiner was not able to locate this

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article in order to refer to it properly by author and journal title. As a result, in this communication, said reference is referred to as D2. The Examiner has employed this reference as prior art because the Applicant has submitted this reference as prior art.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 5, 10, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by “D2”.

D2 teaches that larva eats the bamboo material inside the bamboo and as a result the harmed bamboo now has feces and water accumulated in its rings (page 48, section 2.18). Thus the *P. temminckii* frass is in an aqueous medium meeting the limitations of claims 1, 3, 4, 5, and 11.

No patentable weight is given for the “intended use” of the pharmaceutical composition containing an extract of *P. temminckii* frass as recited in claims 4, 5, and 11. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process

steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Claim 10 is a product by process claim. The product anticipates the claim.

Determination of patentability in "product-by-process" claims is based on product itself, even though such claims are limited and defined by process, and thus product in such claim is unpatentable if it is same as, or obvious from, product of prior art, even if prior product was made by different process. *In re Thorpe*, et al., 227 USPQ 964 (Fed. Cir. 1985)

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over D2 in view of Nobuyuki et al. (JP2000333619) as applied to claims 1, 3, 4, 5, 10, and 11 above and further in view of Holtshousen (US Patent No. 4,671,957).

D2 is discussed above.

D2 does not teach the composition comprising the extract of *P. temminckii* frass as a skin cream.

Nobuyuki teaches isolating a substance having antibacterial properties isolated from the excrement of a stag beetle at concentrations of 10-30% (abstract).

Holtshousen teaches an antibacterial cream that is used topically in the treatment of burns and other skin orders (abstract; column 1, lines 25-30).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the frass of *P. temminckii* as taught by D2 and used it as a skin cream as taught by Noboyuki and Holtszousen.

The amounts of the frass extract are deemed to be manipulatable parameters practiced by a person skilled in the art to obtain the best possible formulations.

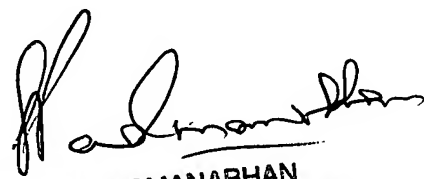
### **Conclusion**

Claims 1-5, 10, 11, 17, and 18 are not allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY STUCKER can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER